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CLINICAL PERFORMANCE AND NEWBORN DATA OF A NEWLY DEVELOPED CLOSED VITRIFICATION DEVICE, CRYOTOP CL FOR HUMAN EMBRYO VITRIFICATION

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【Objective】Vitrification is a freezing method that is applied in almost every IVF clinic. In Japanese facilities, human embryos are usually vitrified by an open device, Cryotop (Top), method in which solution containing embryos is directly exposed to liquid nitrogen. This method does not completely eliminate the risk of cross-contamination between samples. Meanwhile, closed devices have an extremely low risk of contamination across frozen samples. However, the existing closed devices sold in the market require wider space for storage due to their structure, resulting in higher storage cost. Therefore, we developed a new downsized closed vitrification device, Cryotop CL (CL), to solve the problem. In the present study, clinical outcome and newborn data between the two methods, CL and Top, were compared to investigate if the CL can be applicable without sacrificing the potential of embryos after vitrification.

【Design】Prospective study.

【Materials and Methods】The present study was clinically performed, using vitrified-warmed 1505 day 3 embryos (D3) and 1158 blastocysts (BL) of 1198 patients from August 2015 to April 2017. They were randomly allocated either CL (D3: n=995, BL: n=510) or Top (D3: n=510, BL: n=561) and vitrified-warmed. Survival rates at each stage and pregnancy rates of single blastocyst transfer were compared between the two methods. In evaluation of pregnancy rate, over 39-year old patients were excluded. The newborn data was collected from 406 singletons born after vitrified-warmed embryo transfers. Birth height, birth weight, gestation age, sex ratio and congenital abnormalities were respectively compared between CL (n=141) and Top (n=265).

【Result】There were not significant differences in survival rates of D3 (99.0% vs 98.8%) and BL (99.3% vs 98.6%) between CL and TOP. Pregnancy rates of CL and TOP were similar, being 49.8% vs 49.1%, respectively. Furthermore, significant differences were not confirmed between CL and Top in the newborn data such as birth height (48.7 ± 2.3 cm vs 48.4 ± 2.4 cm), birth weight (3024.2 ± 472.3 g vs 3057.4 ± 464.4 g), gestation age (38.8 ± 1.9 weeks vs 38.7 ± 1.7 weeks), sex ratio (50.4% vs 49.4%) and congenital abnormalities (1.5% vs 4.7%).

【Conclusion】 The present study demonstrates that a newly developed closed device, Cryotop CL, does not impair not only developmental potential of D3 and BL after warming, but also pregnancy and fetal development compared to a conventional Cryotop method. Therefore, it is concluded that the CL which is smaller than the existing closed devices is a favorable device for storage cost, safety of patients and performance.